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San Jose, CA 95138
t: 408 754 2000 f: 408 754 2521

stryker®

Endoscopy

JUL 20 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: March 30, 2007

Contact Person:
Erica A. Walters, RAC
Sr. Regulatory Representative
408-754-2078(phone)
408-754-2521 (fax)
erica.walters@stryker.com

Device Name:

Proprietary Name:	Stryker PEEK TwinLoop Tac
Common and Usual Name:	PEEK Suture Anchor
Classification Name:	Screw, Fastener, Fixation, Nonabsorbable, Bone, Soft Tissue (Class II, 21 CFR 888.3040, Product Code MBI, Orthopedics Review Panel)

Predicate Device(s):

Arthrex PEEK SutureTak: K971723, K000506, K050749, K061863
Arthrex Bio-Corkscrew FT: K043337

Device Description and Intended Use:

The Stryker PEEK TwinLoop Tac is intended to be used for suture or tissue fixation in the foot, ankle, knee hip, hand wrist, elbow, and shoulder. Specific indications are listed below and are size appropriate per patient needs:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, digital tendon transfers, Mid-foot reconstruction.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Pelvis: Bladder Neck Suspension for Female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Hip: Capsular repair, acetabular labral repair.

The Stryker PEEK TwinLoop Tac is intended for single-use only.

The Stryker PEEK TwinLoop Tac is a push-in type implant with two USP#1 high strength suture eyelets pre-threaded with USP#2 non-absorbable braided surgical sutures and pre-assembled on a disposable inserter. The Stryker PEEK TwinLoop Tac will be manufactured from PEEK-OPTIMA® LT3 (polyetheretherketone), a biocompatible polymer manufactured by Invibio Inc. The sutures will be USP braided ultra high molecular weight polyethylene (UHMWPE) suture (K033654, K040472 and K063778). The Stryker PEEK TwinLoop Tac will be validated to a SAL of 10^{-6} using ethylene oxide. The EtO residuals will be tested according to ISO 10993-7:1995.

Prior to introducing the Stryker PEEK TwinLoop Tac to market, the device will conform to the following voluntary safety and performance standards: ISO 10993-1, Blue Book Memorandum G95-1, EN 550, EN 556-1, EN 11607-1, EN 11607-2, EN 980, EN 1041, and EN ISO 14971.

The technological and material differences between the Stryker PEEK TwinLoop Tac, and the Arthrex PEEK SutureTak (K971723, k000506, k050749, K061863), do not affect the safety and efficacy of the product; therefore, the Stryker PEEK TwinLoop Tac is considered substantially equivalent in performance, intended use, safety, and efficacy to the Arthrex PEEK SutureTac.

The Stryker PEEK TwinLoop Tac is considered substantially equivalent in material composition, intended use, safety and efficacy to the Arthrex PEEK SutureTak (K971723, k000506, k050749, K061863).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2007

Stryker Endoscopy
% Mr. K. Jeffrey Semone
Director, Regulatory Affairs
5900 Optical Ct.
San Jose, CA 95138

Re: K070882
Trade/Device Name: Stryker PEEK TwinLoop Tac
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC, JDR
Dated: July 6, 2007
Received: July 9, 2007

Dear Mr. Semone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

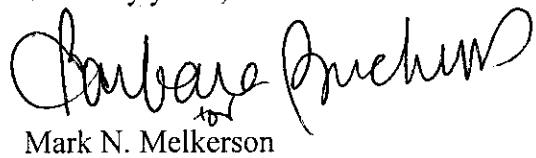
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

Device Name: Stryker PEEK TwinLoop Tac

510(k) Number if known: K070882

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Hip: Capsular repair, acetabular labral repair.

The Stryker PEEK TwinLoop Tac is intended for single-use only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	No

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K070882 Barbara Burns

(Division Sign-Off)
Division of General, Restorative and Neurological Devices